

SENIOR EXECUTIVE (ANALYTICAL RESEARCH AND DEVELOPMENT)

About Bluefish Pharmaceuticals

Founded in Sweden, with its long tradition of industrial entrepreneurship, Bluefish Pharmaceuticals has become one of the most progressive generics pharmaceuticals companies. At Bluefish, we strive to make quality medicine accessible to more people.

Bluefish creates value in the full pharmaceutical value chain from developing to manufacturing and successfully marketing generic pharmaceuticals and we take pride in doing this in an innovative, responsible and cost-efficient way. Bluefish currently conducts operations in 19 countries in Europe and, over the next few years, will also expand outside Europe with the aim of becoming a global player.

Our corporate culture and close collaboration with development and manufacturing partners are integral parts of our effort to deliver quality products at affordable prices.

We offer a product portfolio consisting of a broad range of high quality generics for all major therapeutic areas. It is part of our long-term strategy to expand the product portfolio of off-patent blockbusters while at the same time offering a broader range of niche products within more narrow disease areas.

Bluefish products all originate from a generic substance, where the efficacy and safety are well documented. Through our many collaborating partners, we have access to a vast range of technology platforms, enabling us to develop and enhance the intellectual property of our product portfolio.

Our strategy of developing products based on well-known substances with an improved value to patients results in a product portfolio with a significant market potential. We achieve this with a relatively short development time, low risk, and limited investment.

By focusing on innovation and simplicity in both thought and action, and by taking responsibility on all markets and cost efficiency in all stages, we are creating a strong and vibrant brand that offers quality pharmaceuticals at prices affordable to all.

Bluefish provides quality generic pharmaceuticals at affordable prices. Its product portfolio contains a wide range of products within all major therapeutic areas.

Since its inception, Bluefish has developed the platform and know-how to participate in and to be an integral part of all major steps of the value chain in the offering of generic pharmaceuticals. With the vision of offering quality pharmaceuticals at prices affordable to all, we have to be innovative and at the same time cost-efficient in all stages. This includes operational excellence in departments such as product development, quality assurance, pharmacovigilance, IP and supply chain as well as marketing and sales.

Profile Description

Bluefish is looking for profiles to fill the position of Senior Executive (Analytical Research & Development), contributing to the accomplishment of the Analytical R&D function objectives. The position will report to senior manager Analytical Research and Development. The role would be involved in the below mentioned areas:

- Execute Analytical Method Development activities of drug products based on QbD principles and regulatory requirements.
- Execution of Analytical Method validation activities for drug products as per the regulatory requirements.
- Execute routine Analytical Research activities of drug products.
- Establishing In-house systems and procedures to ensure cGLP practices & regulatory requirements for analytical activities at In-house R&D facility.
- Trouble shooting related to Testing methods, Stability studies, test results and designing of additional experimentations as necessary
- Execution & coordination for Analytical method transfer activities of drug products.

- Calibration of the Analytical instruments as per the master calibration schedule.
- Technical assessment & Analysis of drug substances (API) for projects execution.
- Review & clearance of technical documents leading to dossier batches executions and registrations.
- Preparation and review of Specifications, Method of analysis procedures and Analytical development reports.
- Preparation and review of analytical protocols and reports (Analytical method validation, Method feasibility, Analytical method transfer, etc.).
- Technical assessments of projects (Screening, pipeline and development projects stages) & Literature search).
- Preparation of analytical technical documents for dossier / Technology transfer executions / Regulatory submissions of projects.
- Assisting and resolving technical queries raised during Technology transfer activities & regulatory submissions.
- Assisting in establishment of In-house Infrastructure (Analytical equipments Qualifications and preparation of SOP's).
- Assessment & coordination on regulatory deficiencies.
- Assisting with analytical requirements in finalization of project costings.
- Assisting in assessment of CDO's, Analytical testing labs, CMO's & CRO's
- Technical support and clarifications to CDO's, Analytical testing labs, CMO's.

Candidate Specifications

Education and Experience

- Post graduate in Science /Chemistry / Analytical chemistry/ Pharmacy, with 4 - 6 years of relevant experience in Analytical Research and Development for regulatory market
- Expertise in analytical method development, validations and transfers.
- Excellent computer skills, including Word and Excel in a Microsoft Windows environment and relevant instruments software handling.
- Excellent in interpersonal skills

Skills & Abilities Requirements

- Strong conceptual, analytical development and validation skills.
- Good communication (verbal, writing) and presentation skills.
- Must have ability to work under pressure, meet deadlines, and work on multiple projects simultaneously.
- Must be a team player and be able to interact with staff at all levels of the company and with external parties as well.
- Must have ability to work independently.
- Adequate Job knowledge and exposure to different Analytical methods and instrumentations.
- Adequate Job knowledge and exposure to QbD, DoE and statistical interpretation etc.,
- Willingness and ability to travel approximately 10-20% of time.

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